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**REMARKS**

Claims 1-10 were presented for examination in the present application. The instant amendment adds new claims 11-16. Thus, claims 1-16 are presented for consideration upon entry of the instant amendment.

The specification has been amended to correct obvious errors. Claims 1-10 have been amended so that the preamble better conforms to U.S. practice. It is submitted that these amendments merely make explicit what had been implicit.

Independent claim 1, as well as dependent claims 6 and 8, were rejected under 35 U.S.C. §102 over U.S. Patent No. 4,538,920 to Drake (Drake).

Applicants respectfully traverse this rejection.

Claim 1 is directed to a "device for producing medicinal foam". In contrast, Drake is a multiple-barreled resin dispensing device that simply fails to disclose or suggest the claimed device.

For example, claim 1 recites, in part, that "the two pistons are interconnected through a connecting element which opens one of the chambers when it is displaced".

Drake fails to disclose or suggest the claimed two pistons that are interconnected through a connecting element.

In contrast, Drake discloses a syringe 1 has two parallel internal chambers, each of which is intended to be filled with one part of a two-part polymerizable material, e.g., polymerizable resin. The two internal chambers in syringe 1 are separated by a barrier 4. When a pair of plungers 6 are forced into the two internal chambers in syringe 1, respectively, the contents of the each chamber exits via outlet 2 through outlet passages 3 and 5, flow through static mixing element 7 and exit conduit 9, and are

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intimately mixed to form a homogeneous mass which will rapidly polymerize following expulsion from outlet 11 of exit conduit 9. See col. 3, lines 9-24.

Clearly, the syringe of Drake has two separate plungers 6 that are not "interconnected through a connecting element" as claimed.

Further, the Office Action asserts that barrier 4 of Drake reads on the claimed "piston". Clearly, the barrier 4 of Drake is not a "piston" as claimed.

Accordingly, Applicants submit that claim 1, as well as claims 2-11 that depend therefrom, are not disclosed or suggested by Drake. Reconsideration and withdrawal of the rejection to claims 1-11 are respectfully requested.

Independent claim 1, as well as claims 6-8, were rejected under 35 U.S.C. §103 over U.S. Publication No. 2002/0101784 to Edwards et al. (the Edwards '784 publication) in view of U.S. Patent No. 5,454,805 to Brony et al. (Brony). Dependent claims 2, 5, and 9-10 were rejected under 35 U.S.C. §103 over U.S. Publication No. 2002/0101785 to Edwards et al. (the Edwards '785 publication). Dependent claims 3-4 were rejected under 35 U.S.C. §103 over the Edwards '785 publication in view of U.S. Patent No. 2,724,383 to Lockhart (Lockhart).

Applicants submit that the Edwards '784 publication is not of record in the present application. Specifically, the Edwards '784 publication was not listed on any PTO-1449 form or any PTO-892 form.

Rather, only the Edwards '785 publication is listed on the PTO-892 form. Further, International Application No. WO 02/058834A1 corresponding to the Edwards '785 publication was cited by Applicants at the time of filing the present application. Thus, from the record, it appears to the Applicants that the Office Action includes a typographical error and refers to the Edwards '784 publication (not cited) instead of referring to the Edwards '785 publication (cited).

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Applicants attempted to contact Examiner Kinnal for clarification of this apparent error at the telephone number provided in the Office Action. Unfortunately, the telephone number provided is not an active USPTO number. Further attempts for clarification of this apparent error were made by contacting Supervisory Examiner Jackson without success.

Accordingly, the Office Action, as best understood by the Applicants, includes various rejections of claims 1-10 over the Edwards '785 publication in view of Brony or Lockhart.

Applicants respectfully traverse this rejection.

Independent claim 1 recites, in part, "a foam producing means connected with the active agent chamber and the gas chamber".

The Office Action acknowledges that the Edwards '785 publication fails to disclose a foam producing means. Rather, the Office Action asserts that Brony discloses the use of a sieve. Further, the Office Action asserts that although Brony only discloses the mixture of two liquids, a gas component could be combined through the sieve.

In sum, the Office Action attempts to modify the device of the Edwards '785 publication (mixes solid and liquid) with the sieve in the device of Brony (mixes two liquids), then further modifies this combination by using a gas.

The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). See also *KSR*, 127 S.Ct. at 1734 ("While the sequence of

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these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls.")

Applicants respectfully submit that the Office Action has failed to meet its burden of establishing a *prima facie* case of obviousness because the Office Action has failed to determine the level of skill in the art.

Presuming *arguendo* that the references show the elements or concepts urged by the Office Action, the Office Action has presented no line of reasoning, and we know of none, as to who one skilled in the art is or why that person viewing the collective teachings of the references would have found it obvious to selectively pick and choose various elements and/or concepts from the several references relied upon to arrive at the claimed invention. Rather, Applicants submit that the collection of references supports the inescapable conclusion that the Office Action has simply pieced the references together to support a rejection on the basis of hindsight.

In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). See also *In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986); *In re Clay*, 966 F.2d 656, 659, 23 USPQ2d 1058, 1060-61 (Fed. Cir. 1992) ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem."); *Wang Laboratories Inc. v. Toshiba Corp.*, 993 F.2d 858, 26 USPQ2d 1767 (Fed. Cir. 1993).

Applicants submit that the Edwards '785 publication is non-analogous art to the Brony and Lockhart references such that the proposed combination of cited art fails to disclose or suggest claim 1.

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Claim 1 is directed to a foam producing means. In contrast, the Edwards '785 publication is directed to a cement mixing device that mixes liquids and solids, while Brony is directed to a medicine vial for needless syringes that mixes two liquids, and Lockhart is a mixing device for segregated liquids intended to be hypodermically injected. Thus, none of the cited art is in the field of Applicants' endeavor, namely producing foams.

Further, Applicants submit that the Edwards '785 publication, Brony, and Lockhart each deal with matter that would not logically would have commended itself to an inventor's attention in considering the problem resolved by claim 1.

More particularly, the Edwards '785 publication is directed to mixing a liquid and a solid component until "the powder component is completely wetted by the liquid". See at least paragraph [0017]. The mixing to ensure a powder is wetted by a liquid resolves a completely different problem from the foam producing means of claim 1.

Further, one looking to modify the device of the Edwards '785 publication (mixing solids and liquids until the solid is completely wetted) would not look to the devices of Brony and Lockhart since they deal with matter that simply would not have logically commended itself to an inventor's attention in considering the problem of foam producing means.

Moreover, it is of critical importance to avoid entraining bubbles in medicines that are to be hypodermically injected such as those disclosed by Brony and Lockhart. Thus, one looking to modify the proposed combination of the device of the Edwards '785 publication and Brony or Lockhart would not be compelled to add a gas since doing so produce a foam, which is contrary to the teaching of Brony and Lockhart.

Thus, Applicants submit that the cited art are non-analogous to one another and to the claimed invention such that the proposed combination of cited art fails to disclose or suggest claim 1.

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Accordingly, Applicants submit that the Office Action has failed to establish a prima facie case of obviousness, has used non-analogous art in its rejection, and has failed to establish or even assert that the combination recited by claim 1 does not produce new and unpredictable results.

Still further, claim 1 recites, in part, "a connecting element which opens one of the chambers when it is displaced". Applicants submit that the cited art fails to disclose or suggest such a connecting element.

The Office Action as best understood appears to assert that handle 34 reads on the claimed "connecting element" by connecting plungers 44 to one another.

Applicants respectfully submit that even though the Edwards '785 publication discloses that handle 34 connects plungers 44 to one another, the Edwards '785 publication does not disclose or suggest that handle 34 "opens one of the chambers when it is displaced" as claimed.

Rather, the Edwards '785 publication discloses that syringes 12 and 14 are normally pre-filled and provided as a kit and that, prior to use, the syringes 12 and 14 include a seal 60 which seals exit port 54 and maintains the sterility of the exit port. See paragraph [0031]. Further, the Edwards '785 publication discloses that, as best seen in FIG. 2 syringes 12 and 14 may be connected by any well known connector 62 after the removal of the seals 60. Thus, the Edwards '785 publication discloses that the chambers of the syringes 12 and 14 are opened by removing the seals 60 before the syringes 12 and 14 are connected via connector 62.

Accordingly, Applicants submit that handle 34 of the Edwards '785 publication has absolutely nothing to do with the opening of the syringes 12 or 14 when the handle is moved. As such, the handle 34 simply fails to disclose or suggest the claimed connecting element which "opens one of the chambers when it is displaced".

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As such, Applicants submit that claim 1, as well as claims 2-10 that depend therefrom are allowable over the proposed combination of cited art. Reconsideration and withdrawal of the rejection to claims 1-10 are respectfully requested.

Claims 11-16 have been added to point out various aspects of the present application. Support for new claims 11-16 can be found at least in original claims 1-10, as well as in the specification at page 5, line 7 through page 7, line 26. No new matter is added

Applicants specifically point out that new claims 11-16 are not intended to be limited to the specific mechanisms of patentability previously argued with respect to any previously claim. Accordingly, Applicants hereby rescind any disclaimer of claim scope and, thus, any prior art for which such a disclaimer was made to avoid may need to be revisited by the Examiner with respect to new claims 11-16.

It is believed that new claims 11-16 are in a condition for allowance.

For example, claims 11 and 16 each recite that "the active agent chamber and the gas chamber are arranged one after the other", which is not disclosed or suggested by the cited art.

Independent claim 12 recites, in part, that "wherein the hollow needle interconnects the first and second pistons in common to feed active agent through the hollow needle and gas through the openings to the foam producing device upon displacement of the hollow needle through the first piston to a point where the entrainment element contacts the first piston". Applicants submit that the cited art fails to disclose or suggest the hollow needle as recited by claim 12.

Further, claim 13 recites that "the foam producing device is removably connected to the second piston by a holder". Applicants submit that the cited art fails to disclose or

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suggest the holder that removably connects the foam producing device and the second piston as recited by claim 13.

Moreover, claim 15 recites that the holder has a foam exit opening that comprises "a Luer to which a conventional syringe is connectable", which is not disclosed or suggested by the cited art.

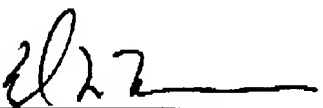
Accordingly and for at least these reasons, claim 12, as well as claims 13-16, are each patentable over the cited art.

In view of the above, it is respectfully submitted that the present application is in condition for allowance. Such action is solicited.

If for any reason the Examiner feels that consultation with Applicants' attorney would be helpful in the advancement of the prosecution, the Examiner is invited to call the telephone number below.

Respectfully submitted,

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